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SIES

College of Arts, Science & Commerce

RISE WITH EDUCATION

Sion (West), Mumbai – 400022

(Autonomous)

Faculty: Science

Program: M.Sc.-I

Subject: BIOANALYTICAL SCIENCES

Academic Year: 2019 – 2020

Choice Based Credit System approved by Board of Studies in Bioanalytical Sciences
Effective from Academic Year: 2019-20

M.Sc. Bioanalytical Sciences Syllabus (Autonomous)

Semester I and Semester II

(Choice Based Credit System, with effect from academic year 2019-20)

Preamble

"I cannot teach anybody anything, I can only make them think" – Socrates

Academic Autonomy signifies a paradigm shift to academic freedom which is instrumental in promoting academic excellence. This paradigm shift served as an impetus for restructuring and refining the curriculum for the postgraduate program in the subject of Bioanalytical Sciences. A clarity of the basic concepts of science is a requisite to build a strong foundation in scientific knowledge. This syllabus will offer students to acquire an in depth knowledge of the subject and also help them equip with the skills and attitudes necessary to enhance their competencies in this technological revolution.

Some topics like Drug discovery and development, Pharmacokinetics, Pharmacodynamics and Drug properties have been included in this syllabus with the purpose to correlate pharmacology with related sciences such as Genomics, Proteomics and Bioinformatics. It will help students recognize and reinterpret the actions and uses of drugs in light of advances in medicine and the basic biomedical sciences. The topics such as Chromatography and Spectroscopy included in the syllabus will expose students to the vast arena of technological improvements in method development and method validation of drugs in pharmaceutical industries.

This syllabus is a collective and constructive effort of the faculty, experts from industry and research institutions and the board members whose valuable suggestions and expertise were instrumental in materializing this syllabus. The comments and recommendations of the contributors and reviewers have been carefully considered and implemented wherever feasible. The syllabus was approved by the Board of Studies in the subject of Bioanalytical Sciences, in the meeting held on 23rd March 2019 at SIES College of Arts, Science and Commerce (Autonomous), Sion, Mumbai.

By implementing this course, we not only want to fulfil the aspirations of postgraduate students who want to pursue careers in fields related to Pharmaceuticals, Nutraceuticals and allied Industries, but we also expect to furnish them with skills and understanding essential to make them self-sufficient and build a satisfying career. Through implementation of this syllabus, we expect students to recognize the links between the various aspects/ topics of the subject that is crucial in gaining a better understanding and in application of the subject.

In conclusion, we hope this syllabus will inculcate an interdisciplinary approach in students and develop a mind for scientific inquiry aspiring to explore new dimensions of the subject. Moreover, this syllabus will also encourage and maximize learning among students to develop open, inquiring minds.

Dr. Satish Sarfare
Chairman,
Board of Studies in the subject of Bioanalytical Sciences

Members of the Board of Studies in the subject of Bioanalytical Sciences and Syllabus Committee

- ✓ *Professor (Dr.) Savita Kulkarni – Scientific Officer (H), Homi Bhabha National Institute, Head, Tuberculosis Immunology & Immunoassay Development Section and Medical Cyclotron & Radiopharmaceutical ProductionSection, Radiation Medicine Centre, BARC (Vice Chancellor's Nominee)*

- ✓ *Professor (Dr.) Sunita Shailajan – Former Head, Department of Botany, Research Project Coordinator, HerbalResearch Lab, Ruia College, Mumbai (Subject Expert from outside college for special course of study)*

- ✓ *Dr. Sasikumar Menon – Director, Institute for Advanced Training & Research in Interdisciplinary Sciences (IATRIS), (Therapeutic Drug Monitoring Lab), Sion, Mumbai; Faculty, Pharma Analytical Sciences, Ruia College, Mumbai (Subject Expert from outside college for specific course/special course of study)*

- ✓ *Dr. Naomita Dhume – Head, Department of Bioanalytical Sciences, Khalsa College, Mumbai (Subject Expert from other college)*

- ✓ *Dr. Ajit Datar – Currently Advisor, Borosil Ltd; Former Advisor, Shimadzu Analytical Pvt Ltd (Subject Expert and Industry representative)*

- ✓ *Mr. Hemant Deshpande – CEO, Pollux Life Sciences Solutions, Mumbai (Representative from Corporate sector / Allied area)*

- ✓ *Dr. Kamalakar Sonawne- Consultant, Pharmaceutical industry (Subject expert and industry representative)*

- ✓ *Dr. Juliet Victoria – Post doctoral fellow, Chemical Engineering Department, Copenhagen, Denmark(Postgraduate Meritorious Alumnus)*

- ✓ *Dr. Tara Menon – Head, Department of Biotechnology, SIES College, Mumbai*

- ✓ *Dr. Pallavi Roy – Faculty, Department of Chemistry, SIES College, Mumbai*

- ✓ *Ms. Pracheta Salunkhe – Faculty, Department of Bioanalytical Sciences, SIES College, Mumbai*

- ✓ *Mr. Tejas Karandikar – Faculty, Department of Bioanalytical Sciences, SIES College, Mumbai*

- ✓ *Dr. Satish Sarfare – Coordinator and Faculty, Department of Bioanalytical Sciences, SIES College, Mumbai*

M.Sc. Bioanalytical Sciences Syllabus (Autonomous) – Semester I and Semester II
Choice Based Credit System (With effect from academic year 2019-20)

Paper Code	Unit No.	Unit Name	Credits	Lectures/week
SIPSBN11	1	Indian systems of Medicine (ASU)-Ayurveda, Siddha & Unani	4	1
	2	Modern Medicine		1
	3	Pharmacognosy		1
	4	Principle of extraction and Isolation of analytes		1
SIPSBN12	1	Good Laboratory Practice (GLP)	4	1
	2	Pharmacopeial standards and Testing Procedure		1
	3	Drug Act & Regulations		1
	4	Quality Control (QC) and Quality Assurance (QA)		1
SIPSBN13	1	Theory of Chromatographic separation and TLC	4	1
	2	HPLC-I		1
	3	GC-I		1
	4	Spectroscopy-I		1
SIPSBN14	1	OMICS	4	1
	2	Electrophoresis		1
	3	Bioinformatics		1
	4	Environmental Issues of Bioanalytical Laboratory		1
SIPSBNP11	Different Medicinal Systems, Pharmacognosy & Extraction Techniques		2	4
SIPSBNP12	GLP, Drug Act and Quality Management		2	4

SIPSBNP13	Chromatography and Spectroscopy- I	**2**	**4**
SIPSBNP14	Proteomics, Bioinformatics & Environmental Issues	**2**	**4**
Total		**24**	**32**

Paper Code	Unit No.	Unit Name	Credits	Lectures/week
SIPSBN21	**1**	R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry	**4**	**1**
	2	Solid Phase Extraction (SPE)		**1**
	3	Phytochemistry		**1**
	4	Supercritical Fluid Extraction (SCFE) and SCFC (Supercritical Fluid Chromatography)		**1**
SIPSBN22	**1**	IPR and Patenting- I	**4**	**1**
	2	Stability Studies		**1**
	3	IPR and Patenting- II		**1**
	4	Packaging in Pharma industry		**1**
SIPSBN23	**1**	HPTLC	**4**	**1**
	2	HPLC-II		**1**
	3	GC-II		**1**
	4	Spectroscopy- II		**1**
SIPSBN24	**1**	NCE and its development into a New Drug and Enzymes	**4**	**1**
	2	Immunoassay & ELISA		**1**

	3	Basic Pharmacokinetics, pharmacodynamics and Drug properties		**1**
	4	Laboratory safety measures w.r.t handling of chemicals and biological materials		**1**
SIPSBNP21	Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques		**2**	**4**
SIPSBNP22	IPR and Patenting, Stability Studies and Packaging		**2**	**4**
SIPSBNP23	Chromatography and Spectroscopy- II		**2**	**4**
SIPSBNP24	New Drug Development, Immunoassays Pharmacokinetics, Laboratory Safety Measures		**2**	**4**
Total			**24**	**32**

SIES College of Arts, Science and Commerce
(Autonomous), Sion (West), Mumbai – 400022

Programme: Master of Science, M.Sc. Part 1 – Bioanalytical Sciences

"I did not think, I experimented"- Wilhelm Röntgen

The characteristic graduate attributes comprising of Programme Outcomes, Programme Specific Outcomes and Course Outcomes for a Science Post Graduate in the subject of Bioanalytical Sciences are as follows:

Note the list of abbreviations:
PO: Programme Outcome, PSO: Programme Specific Outcome, CO: Course Outcome
Cognitive Levels: - R: Remember, U: Understand, Ap: Apply, An: Analyze, E: Evaluate, C: Create

Serial Number	**Details of Programme Outcomes (POs)**
PO1 *(Skill Level)*	Problem Solving Ability *(U, Ap)* • Apply the knowledge of various courses learned under a program to break down complex problems into simple components. • Adopt and assimilate problem-based learning models and apply one's learning to solve real life problem situations.
PO2 *(Skill Level)*	Critical Thinking *(U, An, E)* • Develop critical thinking based on a rationale to identify assumptions, verifying the accuracy and validity of assumptions, and making informed decisions. • Inculcate the ability of logical reasoning to question the rationale behind concepts, ideas, and perspectives.
PO3 *(Skill Level)*	Effective Communication Skills *(Ap, C)* • Improve written and oral communication skills so as to express thoughts and ideas effectively. • Demonstrate the ability to listen carefully and imbibe soft skills to convey and receive instructions clearly. • Develop presentation skills to present complex information in a clear, lucid and concise manner.
PO4 *(Skill Level)*	Proficiency with Information and Communication Technology *(U, An, E)* • Demonstrate ability to access, evaluate and use a variety of relevant information resources inclusive of internet and electronic media for the purpose of collating and analyzing data. • Understand the scope and limitations of tools or software used in Information and Communication Technology.
PO5 *(Skill Level)*	Leadership Skills and Team Work *(U, Ap, An, C)* • Demonstrate leadership skills formulating an inspiring vision, thereby building a team, motivating and inspiring team members to engage and achieve that vision. • Develop management skills to guide people in takings tasks to their logical conclusion. • Inculcate the ability to facilitate coordinated effort as a group or team in the interests of common cause and recognize the contribution of team members.
PO6 *(Attitude Level)*	Self-directed and Lifelong Learning *(U, Ap, An)* • Demonstrate the ability to work independently and take responsibility for one's actions.

	• Acquire the ability to explore and evolve by becoming self-sufficient and self-reliant. • Adapt lifelong learning approaches to broaden one's horizons for personal growth and development.
PO7 *(Attitude Level)*	Ethical Values and Environmental Concerns *(U, Ap, E)* • Embrace moral or ethical values in conducting one's life and implement ethical practices in all aspects of life. • Create awareness and concern for environmental and sustainability issues. • Understand and realize the significance and relevance of co-habitation and co-evolution in attaining the needs of sustainable development.
PO8 *(Attitude Level)*	Gender Sensitization and Community Service *(U, Ap, An)* • Respect gender sensitivity, gender equity and gender justice. • Encourage mutual understanding and express empathetic social concern towards different value systems and different strata of society. • Engage in community service through Institutional Social Responsibility.

Serial Number	**Details of Programme Specific Outcomes (PSOs)**
PSO1	Conceptual Understanding and Emerging Applications *(R, U, Ap, An)* • Understand the nature and basic concepts of quality, drug regulations, environmental safety, omics among other topics, so as to establish the basic foundations of an academia-industry connect. • Demonstrate interest in different disciplines in Bioanalytical Sciences so as to analyze the scope of emerging applications in genetics, food industry, pharmaceutical industry, etc. and apply appropriate methodologies with cutting edge tools/techniques in biological and chemical sciences to seek solutions to emerging problems faced by mankind. • Demonstrate the relevance of the procedural subject knowledge that creates different types of professionals related to the disciplinary/subject areas of Bioanalytical Sciences, including professionals engaged in research and development, teaching, entrepreneurship and in the industry.
PSO2	Analytical reasoning and Scientific Inquiry *(U, An, E)* • Inculcate a sense of inquiry and capability for asking relevant or appropriate questions, articulating problems or concepts or questions. • Encourage the ability to analyze, interpret and draw conclusions from qualitative/quantitative data and critically evaluate ideas, experiences, theories and concepts by following the scientific approach to knowledge development from an open minded and reasoned perspective. • Develop analytical skills involving paying attention to detail and imbibe the ability to construct logical arguments using correct technical language related to the relevant subject. • Analyze and interpret data/information collected or related to experiments or investigations, using appropriate methods involving Biostatistics, Bioinformatics among others and report accurately the findings of the experiment/investigations while relating the conclusions/ findings to relevant theories of Bioanalytical Sciences.
PSO3	Laboratory Skills and Fieldwork *(R, U, E, C)* • Understand and apply standard operating procedures as per Good Laboratory

	Practices so as to develop laboratory skills and qualities required for successful career in teaching, research, industry, etc. • Demonstrate awareness regarding animal ethics, human ethics (in the context of Good Clinical Practices), conservation of flora and fauna, so as to promote safe environment and ecosystem, in the pursuit of disciplinary knowledge. • Develop instrumentation handling skills and laboratory techniques relevant to academia and industry; integrate knowledge, skills with technical competency, so as to create solutions for issues and problems related to biological sciences. • Demonstrate leadership qualities, command trust and respect, thereby, motivating and inspiring team members to work effectively in diverse teams during group projects. Realize the relevance of participation in industrial visits in the context of understanding the theoretical concepts as well as life in the real world.
PSO4	Research Aptitude and Interdisciplinary Approach *(Ap, An, E, C)* • Inculcate and adapt to research aptitude and culture, integrate research-based knowledge in an interdisciplinary framework, and realize the relevance of choosing research as an alternative career option. • Demonstrate the awareness regarding compliance with research ethics, awareness about conflicts of interests and Intellectual Property Rights, and avoiding unethical behavior such as fabricating, falsifying or misrepresenting data or to committing plagiarism. • Inculcate the ability to recognize cause and effect relationships, formulate hypothesis, reporting the results of an experiment or investigation, and application of research tools for analysis and interpretation of data. • Inculcate an interdisciplinary approach, to understand and consolidate fundamental concepts through an inquiry-based curriculum, develop critical thinking and problem-solving ability required to solve different types of biology related problems with well-defined solutions, and tackle open-ended problems that may cross disciplinary-area boundaries.

Course Outcomes for M.Sc. Part 1

At the root of all (science) education (Core Learning Outcome):

"The virtues of science are skepticism and independence of thought"- *Walter Gilbert*

Semester I – Theory

Course Code: SIPSBN11
Course Name: Different Medicinal Systems, Pharmacognosy & Extraction Techniques

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	Cognitive Level	Affinity with PO/ PSO
CO1: • To understand what traditional medicines are.	*R, U, An*	*PO3, PO4, PO6* *PSO1, PSO3*
CO2: • Comparison of Traditional and Modern medicine with respect to formulations, types and dosage.	*R, U, An*	*PO1, PO3* *PSO1, PSO2*
CO3: • To understand the importance of Pharmacognosy in drug preparation	*R, U, An, Ap, E*	*PO1, PO3* *PSO1, PSO2*
CO4: • Introduction to various theoretical concepts related to extraction and isolation of drug formulation.	*R, U, An, Ap*	*PO2, PO3* *PSO1, PSO3*

Course Code: SIPSBN12
Course Name: GLP, Drug Act and Quality Management

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: • To familiarize students with the basic concepts of Good Laboratory Practices and Laboratory Safety Measures	*R, U, An, Ap*	*PO3, PO6* *PSO1, PSO3*
CO2: • To familiarize students with the basic concepts of Pharmacopoeias	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO3*
CO3: • To familiarize students with the basic concepts of Drug Act, various schedules, electronic signatures, the current scenarios of the drug regulations and to give an insight to students about various rules and regulations which the pharmaceutical industries have to follow.	*R, U, An, Ap*	*PO3, PO4* *PSO1*
CO4: • To familiarize students with basic concept of Quality management and Quality assurance (including various stages of standardization) and to reacquaint them with some basic Quality Control techniques like friability, hardness, pH meter, etc.	*R, U, An, Ap*	*PO3, PO6* *PSO1, PSO3*

Course Code: SIPSBN13
Course Name: Chromatography and Spectroscopy-I

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: • To introduce students to analytical chemistry and instrumentation. • To make students understand general concepts of Chromatography and Spectroscopy in terms of principle and instrumentations involved. • To introduce students to chromatographic techniques along with its application in Thin Layer Chromatography. • Familiarize students with all components of Thin Layer Chromatography**.**	*R, U, An, Ap, E*	*PO3, PO4* *PSO1, PSO3*
CO2: • To understand general concepts of HPLC along with its instrumentation, various types and the recent developments in HPLC.	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO2, PSO3*
CO3: • To understand the general concepts of GC along with its instrumentation and the factors affecting it.	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO3*
CO4: • To introduce students to basic concepts of spectroscopy and various instruments which follow principles of spectroscopy	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO3*

Course Code: SIPSBN14
Course Name: Proteomics, Bioinformatics & Environmental Issues

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: • To provide students with basic insights to the terms "OMICS" and to make students understand various concepts related to OMICS with emphasis on Proteomics and to introduce students to the concepts related to Internet of Things.	*R, U, An*	*PO3, PO4* *PSO1, PSO4*
CO2: • To familiarize students with concepts of Electrophoresis, its principle and applications.	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO3*
CO3: • To make students competent in applying computer skills in field of drug discovery by using tools like Bioinformatics.	*R, U, An, Ap*	*PO1, PO4* *PSO1, PSO2*
CO4: • To understand environmental issues related to Bioanalytical laboratory, rules and regulations to be followed.	*R, U, An*	*PO3, PO7* *PSO1, PSO3*

PRACTICAL

"*Without laboratories, men of science are soldiers without arms.*" – *Louis Pasteur*

The practical course in Bioanalytical Sciences is designed for giving students first hand exposure to the analytical instruments used in the industry, as well as to perform experiments to strengthen the theoretical base.

It is an effort to invigorate a thought process that can analyze and reason for the sake of awareness and allow for the students to enable them to use their critical thinking ability and accordingly interpret the results.

Semester I – Practical

Course Code: SIPSBNP11
Course Name: Practical I based on SIPSBN11

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP11	• Perform liquid-liquid extraction of a modern drug from plasma (e.g. Diclofenac Sodium, Glimiperide, Aceclofenac, Metformin, etc.) • Carry out microscopic evaluation of sections and powders with adulteration and formulation comparison of the following medicinal plants: - 1) *Emblica officinalis* – (Amla - dried fruit) 2) *Vitex negundo* - Leaves 3) *Asteracantha longifolia* – Whole plant 4) *Calotropis gigantea* – Leaves 5) *Phyllanthus amarus* – Whole plant Calculation in terms of percent occurrence of key anatomical characteristics in the powder to be recorded. • Separation of plant pigments using paper chromatography • Determination of sugars / plant pigments by paper chromatography.	*R, U, An, Ap, E*	*PO2, PO6* *PSO1, PSO2, PSO3*

Course Code: SIPSBNP12
Course Name: Practical II based on SIPSBN12

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP12	• Go on a field visit and prepare a field notebook and presentation on the same. • Review a research paper given to you. • Carry out dissolution test, disintegration, hardness and friability on any one tablet preparation • Modify an API by using Sodium dodecyl sulphate buffer and other buffer system (for water soluble and water insoluble drug) and with one modification, carry out tablet preparation with the help of IR Punch and then study all the tests w.r.t. different parameters.	*R, U, An, Ap, E, C*	*PO2, PO3* *PSO1, PSO2, PSO3, PSO4*

Course Code: SIPSBNP13
Course Name: Practical III based on SIPSBN13

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP13	• To carry out Gas Chromatographic separation of solvent mixtures (e.g. Methanol & Ethanol, Toluene & Methanol etc.) • To carry out separation of herbal raw material from its formulation (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Phyllanthus amarus* from LIV 52, *Tribulus terrestris* from Ghokshuradi guggul etc.) by using HPLC • To carry out separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.) by using HPLC • HPLC separation of modern drugs from their combination formulation (e.g. Diclofenac Sodium & Paracetamol, Metformin & Glimiperide etc.) • To quantitatively determine caffeine from a given sample by: - i) UV spectrophotometry ii) HPLC • To carry out IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.) • To study Derivatisation in GC	*R, U, An, Ap, E*	*PO1, PO2, PO4* *PSO1, PSO2, PSO3*

Course Code: SIPSBNP14
Course Name: Practical IV based on SIPSBN14

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP14	• To carry out separation of human serum / plasma proteins / egg white using PAGE (Protein molecular weight determination kit may be used) • To evaluate the given data of protein and nucleic acid sequence using a global database with appropriate search engine / software (e.g. BIOEDIT) and to prepare a report stating the steps involved and a brief analysis of the findings. • To evaluate the given data of peptide sequence using a global database with appropriate search engine / software (e.g. BIOEDIT) and to prepare a report stating the steps involved and a brief analysis on the functional annotation of the peptide. • To make use of tools in Bioinformatics like Clustal omega, BLAST A, Blast O, Fasta, Alignment, Prosite, SCOP, Rasmol, CATH, Identification of Protein, etc. • To carry out separation of proteins using 2D gel electrophoresis • To calculate k_a, k_e, $t_{½}$, C_{max} and t_{max} from the given data • To carry out protein profiling of plant seed by SDS-PAGE	*R, U, An, Ap, E*	*PO2, PO4* *PSO1, PSO2, PSO3*

Semester II – Theory

Course Code: SIPSBN21

Course Name: Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
• **CO1:** To understand the dynamics of the pharmaceutical industry in India, it's current trend, government policies and parameters affecting Pharmaceutical industry in India.	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO2*
• **CO2:** To understand the basis of Solid Phase Extraction, the strategies involved, methods in Solid Phase Extraction and current developments in it.	*R, U, An, Ap, E, C*	*PO1, PO2, PO3, PO4* *PSO1, PSO2*
• **CO3:** To introduce students to basics of Phytochemistry, plant metabolites, its classification and different extraction techniques.	*R, U, An, Ap, C*	*PO1, PO3, PO4* *PSO1, PSO2, PSO4*
• **CO4:** To introduce students to Supercritical Fluid Extraction, Supercritical Fluid Chromatography and their basic concepts, instrumentation and factors affecting them, their benefits and their future prospects.	*R, U, An, Ap*	*PO2, PO3* *PSO1*

Course Code: SIPSBN22
Course Name: IPR and Patenting, Stability Studies and Packaging
The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
• **CO1:** To familiarize students with IPR, Patenting. Basic concepts of TRIPS, International Agreements and current scenario.	*R, U, An, Ap*	*PO1, PO4* *PSO1, PSO4*
• **CO2:** To teach students importance of drug stability and its comparison with ASU drugs.	*R, U, An, Ap, E*	*PO2, PO3* *PSO1*
• **CO3:** To provide insights on IPR with respect to India and world.	*R, U, An, Ap*	*PO1, PO4* *PSO1, PSO4*
• **CO4:** To familiarize students with packaging in Pharmaceutical Industry with respect to needs, rules and regulations.	*R, U, An, Ap*	*PO1, PO3, PO4* *PSO1, PSO4*

Course Code: SIPSBN23

Course Name: Chromatography and Spectroscopy-II

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
• **CO1:** To familiarize students with HPTLC with emphasis being on instrumentation, its application and troubleshooting.	*R, U, An, Ap, E*	*PO1, PO3, PO4* *PSO1, PSO3*
• **CO2:** To familiarize students with HPLC with emphasis being on instrumentation, its application and troubleshooting.	*R, U, An, Ap, E*	*PO1, PO3, PO4* *PSO1, PSO3*
• **CO3:** To familiarize students with GC with emphasis being on instrumentation, its application and troubleshooting.	*R, U, An, Ap, E*	*PO1, PO3, PO4* *PSO1, PSO3*
• **CO4:** To familiarize students with AAS, AES, ICP, CD, ORD, X-ray diffraction with emphasis being on instrumentation, its application and troubleshooting.	*R, U, An, Ap, E*	*PO1, PO3, PO4* *PSO1, PSO3*

Course Code: SIPSBN24
Course Name: Drug Development, Pharmacokinetics, Pharmacodynamics, Drug Properties and Immunoassays, Laboratory Safety Measures

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
• **CO1:** To introduce students to new chemical entity and to other concepts like targets of drug action, personalized medicine, etc.	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO4*
• **CO2:** To introduce to students various concepts of Pharmacokinetics, parameters, techniques and models involved.	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO4*
• **CO3:** To acquaint students with various concepts in Pharmacodynamics like structure activity relationship, mechanisms of drug action, classification of drugs, etc.	*R, U, An, Ap, E*	*PO1, PO3, PO4* *PSO1, PSO2, PSO4*
• **CO4:** To familiarize students with basic concepts of Immunoassay and ELISA and its practical applications.	*R, U, An, Ap*	*PO1, PO3* *PSO1*

Semester II – Practical

Course Code: SIPSBNP21
Course Name: Practical I based on SIPSBN21

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP21	• SPE of a modern drug from formulation (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc. • SPE of a modern drug from plasma (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.) • Prepare specific reagents and conduct qualitative test for the presence of alkaloids, tannins, lignans, steroids and glycosides using TLC. Compare the results using standards (if available). • Preparation of Herbarium of following medicinal plants; *Asteracantha longifolia* *Trigonella foenum* *Clitoria ternatea* *Coriandrum sativum* *Achyranthes aspera* *Scoparia dulcis* *Amaranthus spinosa* *Phyllanthus amarus* *Calotropis gigantea* *Vitex negundo* • Determination of percentage purity of $CaCO_3$/$MgCO_3$ by Titrimetry Complexometry IE chromatography • Comparison of classical and modern method of extraction of phytoconstituent of medicinal plants • Effect of drying on phytoconstituents (Terpenes, alkaloids, tannins, etc.) • Phytochemical variation within a species using HPLC/HPTLC • Preparation of calibration graphs for Li, Na, and K by flame Photometry using their solutions of appropriate concentrations and studying interference of • K in Na estimation OR • Na in Li estimation OR • Li in K estimation	*R, U, An, Ap, E, C*	*PO1, PO2, PO3, PO6* *PSO1, PSO2, PSO3*

Course Code: SIPSBNP22
Course Name: Practical II based on SIPSBN22

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP22	• Go on an industrial visit and prepare a report and presentation on the same. • Draft a patent claim based on the invention given to you. • Accelerated stability studies of various formulations or drugs with respect to (a)Temperature (b) Effect of buffers / pH dependent • Test for degradation of compounds using TLC for any two drugs. • Stability testing of solution and solid dosage forms for photo degradation. • Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. • Stability studies of drugs in dosage forms at 25℃, 60% RH and 40℃, 75% RH and at different pressures	*R, U, An, Ap, E, C*	*PO2, PO3* *PSO1, PSO2, PSO3, PSO4*

Course Code: SIPSBNP23
Course Name: Practical III based on SIPSBN23

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP23	• To carry out separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.) by using HPTLC • To obtain an HPTLC fingerprint of herbal raw material (e.g. *Asteracantha longifolia*, *Ricinus communis*, *Calotropis gigantea*) • To carry out separation of herbal raw material from its formulation (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Phyllanthus amarus* from LIV 52, *Tribulus terrestris* from Ghokshuradi guggul etc.) by using HPTLC • To carry out Gas Chromatographic separation of solutes from their matrix (e.g. Diclofenac sodium from its formulation, Methanol from plasma etc.) • To quantitatively determine caffeine from a given sample by i. HPTLC ii. HPLC iii. UV	*R, U, An, Ap, E*	*PO1, PO2, PO4* *PSO1, PSO2, PSO3*

Course Code: SIPSBNP24
Course Name: Practical IV based on SIPSBN24

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP24	• Carry out HEPALISA to determine the levels of the antigen of the hepatitis virus in serum. • Carry out an immunoassay to determine HCG levels in urine. • Using RIA/IRMA, determine T3 and T4 levels in serum. • Calculate different pharmacokinetic parameters like k_a, k_e, $t_{½}$, C_{max}, t_{max} and AUC from the given blood data.	*R, U, An, Ap, E*	*PO1, PO2, PO4* *PSO1, PSO2, PSO3, PSO4*

M.Sc. Bioanalytical Sciences Syllabus (Autonomous)

Choice Based Credit System (With effect from academic year 2019-20)

Semester I – Theory

Paper Code: SIPSBN11
Different Medicinal Systems, Pharmacognosy & Extraction Techniques

Learning Objectives

- *To understand what are traditional medicines.*
- *Traditional and Modern medicines comparison with respect to formulation, types and dosage.*
- *To understand the importance of Pharmacognosy in drug preparation.*
- *Introduction to various theoretical concepts related to extraction and isolation of drug formulation.*

Unit 1: Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani 15 Lectures

1.1 : Principles and Practice (*History and current scenario, basic principles*)
1.2 : Types of drug formulation (*At least 4 from each branch in detail and various other formulations*)
1.3 : Methods of manufacture – raw material to finished product (*AYUSH Guidelines*)
1.4 : Types of drugs *(Elaboration of 1.2*)
1.5 : Excipients in various dosage forms (*What are excipients, excipients used in ASU drugs, general dosage of ASU drugs*)

References:

- A.F.Rudole Hoernle, Vaidya Bhagwan Dash, *Studies in the Medicine of Ancient India*, Concept Publisher Co.
- Prof. (Mrs) Asima Chatterjee, Dr.Satyesh Chandra Prakash, *The Treatise on Indian Medicinal Plants* Vol 1, Publications & Information Direct
- V.V.Sivarajan, Indira Balachandran, *Ayurvedic Drugs and Their Plant Sources*, Oxford and IBH
- L.D.Kapoor, *Handbook of Ayurvedic Medicinal Plants*, CRP Press
- www.indianmedecine.nic.in
- Howard C.Ansel, *Introduction to Pharmaceutical Dosage Forms* 4th ed., Lea & Febiger
- H.J.Roth, A.Kleemann, *Pharmaceutical Chemistry* Vol 1, Ellis Horwood

Unit 2: Modern Medicine 15 Lectures

2.1 : Principles and Practice (*History and current scenario, basic principles*)
2.2 : API and concept of its formulation into a dosage form (*Definition, difference between API and formulation w.r.t to WHO guidelines. API and dosage general concept*)
2.3 : Different types Drug Formulations (Various forms, at least 4 in detail)
2.4 : Excipients in various dosage forms (*Definition of excipient, its role in formulation and dosage*)
2.5 : Disease Management (Comparison of ASU and Modern Drugs) (*Comparison of unit 2.1 and 2*)

a. Diabetes
b. Tuberculosis
c. Hypertension
d. Hepatitis
e. Malaria

f. Dengue
g. Influenza

References:

- John B. Taylor, Peter D. Kennewell, *Modern Medicinal Chemistry*, Ellis Horwood Ltd
- D.R.Karsa, R.A.Stephenson, *Excipients & Delivery Systems for Pharmaceutical Formulations*, The Royal Society of Chemistry

Unit 3: Pharmacognosy **15 Lectures**

3.1 : Introduction, Plants and their medicinal uses example of one plant to be given (*Examples of plants in practicals)*
3.2 : Concepts of ethanobotany, ethno medicines and pharmacology *(definition, general concept*)
3.3 : Phytogeographical regions to be explained with respect to endemism and hot spots (explain only concepts) (*Concepts of endangered plants, endemic plants and hot spots in india*)

3.4 : Herbaria evaluation to include Plant collection, Authentication, storage and drying techniques. (*Basic concept, BSI, role of Herbaria in drug preparation)*
3.5 : Raw material evaluation to include Microbial load, Raw material characterization, proximate evaluation, photomicrography (*Assays to be done, basic microbiology*)
3.6 : Concepts of GAP and GHP for medicinal plants (only introduction) *(w.r.t AYUSH or WHO guidelines)*

References:

- Varro E.Tyler, Lynn R.Brody, James E.Robbers, *Pharmacognosy* 9th ed., Lea and Febiger

Unit 4: Principle of extraction and Isolation of analytes **15 Lectures**

4.1 : Introduction
4.2 : Physico-chemical properties of drugs and solvents
4.3 : Concept of partition & Partition Coefficient
4.4 : Solvent properties
4.5 : Selection of solvent
4.6 : Extraction efficiency
4.7 : Introduction to classical methods of extraction
4.8 : Introduction to modern methods of extraction- advantages & disadvantages - Include LLE (Soxhlet) and LME
4.9 : Applications of extraction
4.10 : Microwave assisted extraction its advantages and disadvantages
4.11 : Ionization and its effect on the extraction of drugs
4.12 : The 'First law of drug metabolism'
4.13 : Matrix components & analyte isolation
4.14 : Concentration of extracts
4.15 : Isolations of fractions
4.16 : Purification of isolate

References

- Tatsuya Sekine, Yuko, Hasegawa, Dr.V.Mshinde, *Solvent Extraction Chemistry Fundamentals and Applications*, Marcel Dekker Inc

Semester I – Theory

Paper Code: SIPSBN12
GLP, Drug Act and Quality Management

Learning Objectives:

- *To familiarize students with basic concept of Good laboratory Practices, Dug Acts, Pharmacopeia's, Quality management and Quality assurance (various stages involved), various schedule, electronic signature and the current scenario.*
- *To give an insight to students about various rules and regulations which Pharmaceutical industries have to follow.*

Unit 1: Good Laboratory Practice (GLP) 15 Lectures
Laboratory Safety Measures w.r.t handling of chemicals and biological materials

1.1 : What is GLP? (*Definition, importance)*
1.2 : Practicing GLP
1.3 : Guidelines to GLP
1.4 : Documentation of Laboratory work
1.5 : Preparation of SOPs
1.6 : Calibration records (*implementation in laboratory)*
1.7 : significance of validation in GLP
1.8 : Transfer of methods
1.9 : Documentation of results
1.10 : General Precautions, labels and signage
1.11 : Material handling and disposal
1.12 : Material Safety Data Sheets (MSDS) and SOP (Standard Operating Procedure)
1.13 : Personal safety & Clothing
1.14 : Levels of safety
1.15 : Fire safety and fire fighting
1.16 : Working in Biosafety Cabinets and hoods

References:

- R.S.Iyer, *Schedule M and Beyond Good Manufacturing Practices*, Indian Drug Manufacturers Association

Unit 2: Pharmacopeial standards and Testing Procedure 15 Lectures

2.1 : Introduction to WHO guidelines
2.2 : Introduction to Pharmacopoeias IP, BP, USP (JP, EP, AP where ever applicable)
2.3 : Specified test in Monographs w.r.t liquid formulation (injectable) and solid dosage form (USP, EP, BP, IP)
2.4 : Include AP, Indian HP and AFI (wherever applicable)

References:

- Dr.C.R.Karnick, *Pharmacopoeial Standards of Herbal Plants* Vol I, Sri Satguru Publisher
- Regional Research Lab & IDMA, *Indian Herbal Pharmacoepoeia* Vol II, Regional Research Lab
- Dr.C.R.Karnick, *Pharmacopoeial Standards Of Herbal Plants* Vol II, Sri Satguru Publisher .
- Dr.V.Rajpal, *Standardization of Botanicals* Vol I, Eastern Publishers

Unit 3: Drug Act & Regulations **15 Lectures**

3.1 : Indian Drugs and Cosmetics Act w.r.t Schedule Y, M, H. Include Schedule A, S (introduction)
3.2 : Introduction to foreign guidelines w.r.t US, EU, Australia & Japan
3.3 : Introduction to CFR 21 part 11
3.4 : Current guidelines

Unit 4: Quality Control (QC) and Quality Assurance (QA) **15 Lectures**

4.1 : Introduction
4.2 : What is QC? What is QA?
4.3 : Requirements for implementing QC & QA
4.4 : QC & QA concepts in ASU drugs
4.5 : Standardizing an Analytical method
    a. Preliminary requirements of a discriminatory quantitaion
    b. Detection of the analyte of interest
    c. Separation of analyte form the matrix components
    d. Sample preparation for quantitation
4.6 : Factors for standardization
    a. Solid-phase extraction
    b. Extraction sequence
    c. Liquid/liquid extraction
    d. Quantification
4.7 : Support work & documentation
4.8 : Validation
4.9 : Audit requirements, audits and audit reports
4.10: Personnel Responsibility in QA

References:

- Tatsuya Sekine, Yuko, Hasegawa, Dr. V.M. Shinde, *Solvent Extraction Chemistry Fundamentals and Applications*, Marcel Dekker Inc
- F.Bloomfield, R.Baird, R.E.Leak, R.Leech, *Microbial Quality Assurance in Pharmaceuticals,Cosmetics and Toiletries* ,Ellis Horwood

Semester I – Theory

Paper Code: SIPSBN13
Chromatography & Spectroscopy-I

Learning Objectives:

- *Introduce students to analytical chemistry and Instrumentation.*
- *To make students understand general concept of Chromatography and Spectroscopy in terms of principle and instrumentations involved.*
- *To introduce students to chromatographic techniques along with its application in Thin Layer Chromatography. Familiarize students with all components of Thin Layer Chromatography.*
- *To understand general concepts of HPLC along with its instrumentation and various types. Recent development in HPLC.*
- *To understand general concepts of GC along with its instrumentation factors affecting it.*
- *To introduce students to basic concepts of spectroscopy and various instruments which follow principles of spectroscopy*

Unit 1: Theory of Chromatographic separation and TLC **15 Lectures**

1.1 : Principles of chromatographic separation (*general concepts, terminology*)
1.2 : Introduction to chromatographic separation techniques
1.3 : Classification of chromatography (*partition adsorption chromatography)*
1.4 : Principles and Practice of TLC (*types: planar*)
1.5 : Uses of TLC (*applications*)
1.6 : Some recommended solvents systems (*mobile systems*)
1.7 : Detection of compounds on TLC plates (*detecting reagents*)

References:

- Douglas A.Skoog, *Principles of Instrumental Analysis*, Saunders College Publishing
- Dr.P.D.Sethi, *Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography*, CBS Publishers and Distributors
- B.Ravindranath, *Principles and Practice of Chromatography*, Ellis Horwood Ltd
- I.P.Alimarin,V.I.Fadeeva ,E.N.Dorokhora, *Lecture Experiments in Analytical Chemsitry* ,Mir Publishers, Moscow
- William David Cooper,Albert D.Helfrick ,*Electronic Instrumentation and Measurement Technique* ,Prentice Hall of India Pvt.Ltd
- Hobart H.Williard, Lynne Merritt, John Dean, FrankSettle, *Instrumental Methods of Analysis* 6th Ed.,CBS Publishers and Distributors
- P.D.Sethi ,Dilip Charegaokar ,*Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography*, CBS Publishers and Distributors
- H.Wagner, S.Bladt , Zgainski, *Plant Drug Analysis A Thin Layer Chromatography Atlas*, Springer Veriag

Unit 2: HPLC – 1 (*General concepts elaboration w.r.t practicals*) **15 Lectures**

2.1 : Principles and Instrumentation
2.2 : The chromatographic process
2.3 : The chromatogram
2.4 : Separation mode
2.5 : Column chemistry
2.6 : System parameters
2.7 : Reverse-phase HPLC
2.8 : Introduction to various HPLC techniques;

a. Ion-pair HPLC
b. Ion-exchange HPLC
c. Normal-phase HPLC
d. Affinity Chromatography
e. Gel permeation Chromatography

2.9 : Recent advances (Fast LC, online extractions, add on pumps, online derivatization, multi-dimensional LC)

References:

- Edward Johnson, Robert Stevenson, *Basic Liquid Chromatography*, Varian Associate
- B.Ravindranath, *Principles and Practice of Chromatography*, Ellis Horwood Ltd
- Hobart H.Williard, Lynne Merritt, John Dean, Frank Settle, *Instrumental Methods of Analysis* 6th Ed.,CBS Publishers and Distributors
- Douglas A.Skoog, *Principles of Instrumental Analysis*, Saunders College Publishing
- Dennis J. Runser, *Maintaining and Troubleshooting HPLC Systems*, John Wiley and Sons

Unit 3: GC – I (*General concepts elaboration w.r.t practicals)* **15 Lectures**

3.1 : Principles and Instrumentation
3.2 : Factors that affect the chromatographic separation (Temperature, Type of column etc.)
3.3 : GC techniques
3.4 : Types of columns and their application
3.5 : Selection of liquid stationary phases (Packed and capillary columns)
3.6 : GC hardware

a. Introduction to flow and pressure controllers
b. Injection techniques- on column injection, large volume injection, split - split less, PTV and various auto injectors- gas sampling as well as liquid sampling
c. Column Oven- temperature programming, (High /cryogenic oven temperature)

References:

- B.Ravindranath, *Principles and Practice of Chromatography*, Ellis Horwood Ltd
- Roger M.Smith, *Gas and Liquid Chromatography in Analytical Chemistry*, John Wiley and Sons

Unit 4: Spectroscopy – I (*General concepts elaboration w.r.t practicals*) **15 Lectures**

4.1 : Introduction to atomic and molecular Spectroscopy (*Differences between the two*)

4.2 : UV, Visible and fluorescence

i. Principles & Instrumentation
ii. Applications

4.3 : Nephelometry

i. Principles & Instrumentation
ii. Applications

4.4: Turbidometry

i. Principles & Instrumentation
ii Applications

4.5 : IR

Principles & Instrumentation
Applications

4.6 : FTIR

i. Principles and Instrumentation
ii. Applications

4.7 : Basic concepts of NMR spectroscopy

4.8 : Raman spectroscopy

References:

- Douglas A.Skoog, *Principles of Instrumental Analysis*, Saunders College Publishing
- Robert White, *Chromatography / Fourier Transform Infrared Spectroscopy and its Applications*,

Marcel Dekker Inc
- R.W.Hannah, J.S.Swinehart, *Experiments in Techniques of Infrared Spectroscopy*, Perkin Elmer
- Patrick Hendra, Catherine Jones, Gavin Warnes, *Fourier Transform Raman Spectroscopy Instrumentation and Chemical Applications,* Ellis Horwood
- Gordon M.Barrow, *Introduction to Molecular Spectroscopy*, McGraw Hill
- Stephen G.Schulman, *Molecular Luminescence Spectroscopy Methods and Applications Part I,* John Wiley and Sons
- George G.Guilbault, *Practical Fluorescence*, Marcel Dekker
- B.J.Clark, T.Frost ,M.A.Russell ,*UV Spectroscopy Techniques Instrumentation Data Handling*.Chapman and Hall
- W.O.George, H.A.Willis, *Computer Methods in UV Visible and IR Spectroscopy*, Royal Society of Chemistry

Semester I – Theory

Paper Code: SIPSBN14
Proteomics, Bioinformatics & Environmental Issues

Learning Objectives:

- *To provide students with basic insights to the terms "OMICS". To make students understand various concepts related to OMICs with emphasis on Proteomics.*
- *To familiarize students with concepts of Electrophoresis, its principle and applications.*
- *To make students competent in applying computer skills in field of drug discovery by using tools like Bioinformatics.*
- *To understand environmental issues related to Bioanalytical laboratory, rules and regulations to be followed.*

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Unit 1: OMICS **15 Lectures**

1.1 : Introduction to Omics:

a. Genomics
b. Proteomics
c. Metabolomics
d. Lipidomics (*basic introduction and application*)

1.2 : Significance of proteome
1.3 : Overview of proteomics

a. Methods for cell disruption/protein extraction
b. Protein purification/ Fractionation
c. Protein identification and characterization

1.4 : Modification of proteins (in vitro/in vivo)

a. Post translational
b. Chemical

References:

- Rastogi, *Bioinformatics: Methods and applications- Genomics, Proteomics and Drug Discovery*
- Gopal, *Bioinformatics with fundamentals of genomics and proteomics*

Unit 2: Electrophoresis **15 Lectures**

2.1 : Basic Protein Chemistry
2.2 : Principles of electrophoretic separation
2.3 : Equipment and process
2.4 : Agarose gel electrophoresis
2.5 : PAGE – Native & SDS, 2DGE, Extensions of Electrophoresis -Immunoelectrophoresis/pulse field
2.6 : Standardization of electrophoretic technique
2.7 : Detection techniques
2.8 : Applications of electrophoresis

References:

- Allen J.Bard, *Electroanalytical Chemistry,* A series of Advances Volume –5, Marcel Dekker, Inc; New York

- Allen J.Bard , *Electroanalytical Chemistry*, A series of Advances Volume – 12, Marcel Dekker, Inc; New York
- Allen J.Bard, *Electroanalytical Chemistry*, A series of Advances Volume – 13, Marcel Dekker, Inc; New York
- Norberto A.Guzman, *Capillary Electrophoresis Technology*, Marcel Dekker Inc
- Dale R Baker, *Capillary Electrophoresis*, John Wiley and Sons
- H.E.Schwartz, R.H.Palmieri, *Introduction to Capillary Electrophoresis of Proteins and Peptides*, Beckman
- Kelvin Altria and Manus Rogan, *Introduction of Quantitative Applications of C.E in Pharmaceutical Analysis*, Beckman

Unit 3: Bioinformatics **15 Lectures**

3.1 : What is bioinformatics?
3.2 : Databases and Search Tools
3.3 : Applications of bioinformatics
a. Genomics
b. Proteomics
c. Drug discovery (Docking software)
3.4 : Using various libraries & tools w.r.t structure/ literature to drug development/ proteins
3.5 : Introduction to Chemi-informatics.

References:

- Rastogi, *Bioinformatics: Methods and applications- Genomics, Proteomics and Drug Discovery*
- Gopal, *Bioinformatics with fundamentals of genomics and proteomics*

Unit 4: Environmental Issues of Bioanalytical laboratory **15 Lectures**

4.1 : Introduction to types and sources of Laboratory waste

4.2 : Introduction to types and sources of Laboratory waste

4.3 : Chemical & Biological materials: Hazards and Handling

- Chemical Storage and Segregation
- Chemical Laboratory Emergency Response
- Equipment Safety
- Laboratory Inspections
- Transportation and Receiving of Hazardous Materials

4.4 : Hazard Controls & Information (*Workplace Hazardous Materials Information System {WHMIS} as an example)*

4.5 : Introduction to: Regulations of Pollution Control Board for Laboratories.

References:

- Central Pollution Control Board Guidelines

M.Sc. Bioanalytical Sciences Syllabus (Autonomous)
Choice Based Credit System (With effect from academic year 2019-20)

Semester I – Practical I (SIPSBNP11) Based on SIPSBN11

- Liquid – liquid extraction of a modern drug from plasma and formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)

- Microscopic evaluation of sections and powders with adulteration and formulation comparision of the following medicinal plants: -

1) *Emblica officinalis* – (Amla - dried fruit)
2) *Vitex negundo* - Leaves
3) *Asteracantha longifolia* – Whole plant
4) *Calotropis gigantea* – Leaves
5) *Phyllanthus amarus* – Whole plant

Calculation in terms of percent occurrence of key anatomical characteristics in the powder to be recorded.

Individual student must report findings of ANY THREE from the above list but in each institution evaluation on all the listed plants must be carried out.

- Separation of plant pigments using paper chromatography
- Determination of sugars /plant pigments by paper chromatography.

Semester I – Practical II (SIPSBNP12)
Based on SIPSBN12

- Students must submit a Field Note Book of their field excursion including Presentation of the field visit

- Research Paper Review

- Carry out dissolution test, disintegration, hardness and friability on any one tablet preparation

- Modification by using Sodium dodecyl sulphate buffer and other buffer system (for water soluble and water insoluble drug). And With one modification that student should carry out tablet preparation with the help of IR Punch and then study all the test w.r.t. different parameters.

Semester I – Practical III (SIPSBNP13)
Based on SIPSBN13

- Gas Chromatographic separation of solvent mixtures (e.g. Methanol & Ethanol, Toluene & Methanol etc.)

- HPLC separation of herbal raw material from its formulation (e.g. *Asteracantha longifolia* from Lukol / Speman, *Phyllanthus amarus* from Liv 52, *Tribulus terrestris* from Ghokshuradi guggul etc.)

- HPLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)

- HPLC separation of modern drugs from their combination formulation (e.g. Diclofenac Sodium & Paracetamol, Metformin & Glimiperide etc.)

- Determination of Caffeine from a given sample by
  i) UV spectrophotometry
  ii) HPLC

- IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.)

- Derivatisation in GC

Semester I – Practical IV (SIPSBNP14)
Based on SIPSBN14

- Separation of human serum / plasma proteins / egg white using PAGE (Protein molecular weight determination kit may be used)

- Evaluate the given data of protein and nucleic acid sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis of the findings.

- Evaluate the given data of peptide sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis on the functional annotation of the peptide.

- Bioinformatics: Clustal Omega, BLAST A, BLAST O, FASTA, Alignment, Prosite, SCOP, RasMol, CATH, identification of proteins

- Separation of proteins using 2D gel electrophoresis

- Calculation of k_a, k_e, t ½, C_{max} and T_{max} from the given data (2 expts.)

- Protein profiling of plant seed by SDS-PAGE

M.Sc. Bioanalytical Sciences Syllabus (Autonomous)
Choice Based Credit System (With effect from academic year 2019-20)

Semester II – Theory

Paper Code: SIPSBN21
Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques

Learning Objectives:

- *To understand the dynamics of Pharmaceutical industry. Its current trend, government policies and parameters affecting Pharmaceutical industry in India.*
- *Understanding basis of Solid Phase Extraction, strategies involved, methods and current development.*
- *Introduce students to basics of Phytochemistry, plant metabolites, its classification and different extraction techniques.*
- *Introduce students to Super Critical Extraction, its basic concepts, instrumentation and factors affecting it, benefits and future prospects.*

Unit 1: R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry
15 Lectures

1.1 : Historical background with emphasis on Post 1947 period
1.2 : Market trends and activities
1.3: Govt. initiatives and the public sector in Pharmaceutical Industry
1.4 : The role of Drug Pricing policy in India and its impact on the Indian Pharmaceutical Industry
1.5: Role of Analytical chemist in Pharmaceutical Industry
1.6 : R&D strategies of Indian Pharma
1.7 : Pharma R&D
1.8 : Bulk Drug manufacturing & its R&D
1.9: Varied Dosage forms and its R&D

References:

- R.S.Iyer, *Schedule M and Beyond Good Manufacturing Practices*, Indian Drug Manufacturers Association

Unit 2: Solid Phase Extraction (SPE) **15 Lectures**

2.1 : Introduction
2.2 : General properties of bonded silica sorbents
2.3 : Sorbent/analyte interactions
2.4 : Sample pretreatment of different biological matrices**:** Developing SPE methods
2.5 : Example of an SPE method (introduction of SPME)
2.6 : Disc cartridges
2.7: 96-Well Format (e.g. Porvair Microsep TM system)
2.8 : Direct injection of plasma
2.10: Other new developments

References:
Douglas A. Skoog, *Principles of Instrumental Analysis,* Saunders College Publishing

Unit 3: Phytochemistry **15 Lectures**

3.1 : Natural drug substances from plants (primary and secondary metabolites)
3.2 : Broad classification of secondary metabolites

a. Nitrogenous
b. Non nitrogenous
c. Isoprenoids

3.3 : Secondary drug metabolite production with special reference with integrated pathway
3.4 : Key Factors affecting synthesis of secondary metabolites
3.5 : Choice of solvent for extraction of phytoconstituents
3.6 : Extraction Techniques of Crude plant material w.r.t
1) maceration (Types- Kwatha and Swarasa)
2) percolation
3) steam distillation

References:

- Prof. Dr.F.C.Czygan, D.Frohne, C.Hohxel, A.Nagell, H.J., Pfainder, G.Willuhn , W.Buff, *Herbal Drugs and Phytopharmaceuticals*, CRC Press

Unit 4: Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography)
15 Lectures

4.1 The concept of SCFE & SCFC
4.2 : Instrumentation of SCFE & SCFC
4.3 : Factors affecting SCFE & SCFC
4.4 : Benefits of SCFE & SCFC
4.5 : Application of SCFE for natural products and Application of SCFC
4.6: Conclusions and future perspectives

References:

- Larry T. Taylor, *Supercritical Fluid Extraction*, John Wiley and Sons

Semester II – Theory

Paper Code: SIPSBN22
IPR and Patenting, Stability Studies and Packaging

Learning Objectives:

- *To familiarize students with IPR, Patenting. Basic concepts of TRIPS, International Agreements and current scenario.*
- *To teach students importance of drug stability and its comparison with ASU drugs.*
- *To provide insights on IPR with respect to India and world.*
- *To familiarize students with packaging in Pharmaceutical Industry with respect to needs, rules and regulations.*

Unit 1: IPR and Patenting - I **15 Lectures**

1.1 : Concept of IPR - Understanding the meaning of IPR & its significance in knowledge based economy.
1.2 : Types of IPR - Patents, Trade Marks & Service Marks, Design Registration, Trade Secrets, Geographical indications, Protection of New Plant Varieties, Copyright.
1.3 : Global Harmonization - Impact of IPR on global trade and the need for harmonization, WTO and its role in a global harmonization, TRIPS and introduction to the articles in TRIPs document as well as the flexibilities provided by TRIPS.
1.4 : International Agreements related to IPR & patents - Paris Convention, PCT.

References:

- H.Jackson Knight, *Patent Strategy for Researchers and Research Managers* 2nd ed, John Wiley and Sons

Unit 2: Stability Studies **15 Lectures**

2.1 : Factors that influence stability of drug formulations
2.2 : Types of Stability chambers and their design considerations
2.3 : Stability issues of ASU raw materials and finished products
2.4 : Guidelines on Stability evaluations
2.5 : Approaches to stability studies of ASU formulations

References:

- S.F.Bloomfield, R.Baird, R.E.Leak, R.Leech, *Microbial Quality Assurance in Pharmaceuticals,Cosmetics and Toiletries* ,Ellis Horwood
- William Hewitt, Stephen Vincent, *Theory and Application of Microbiology Assay*, Academic Press
- Jens T. Carstensen, *Drug Stability Principles & Practices* 2nd e.d.,Marcel Dekker
- Kenneth A.Connors, Gordon L.Amidon, Valentino J.Stella, Chemical Stability of *Pharmaceuticals*, John Wiley & Sons
- Hamed M.Abdon, *Dissolution Bioavailbaility and Bioequivalence*, MACK Publishers

Unit 3: IPR and Patenting - 2 **15 Lectures**

3.1 : Indian Patent Act -

a. Criteria to be fulfilled for Patentability - new/novel, non-obvious/inventive step, useful/capable of industrial application.
b. Non-patentable subject matter - what is not patentable.
c. Concept of Mailbox and EMR and how it has helped India in its transition to full TRIPS compliance.
d. Role of patentee and patent offices in patent management including lab documentation, confidentiality agreements, pre- and post-grant opposition, servicing of patents.
e. Provisional Patents, Divisional Patents & Patents of Addition.

3.2 : IPR as a strategic tool –

a. Concepts of piracy, reverse engineering and knowledge worker.
b. Benefits of creating and/or owning patents and other IPR.
c. How India has leveraged the flexibilities provided by TRIPS to safeguard the industry and prevent ever-greening of patents.

3.3 : IP clearance – Precautions before launching of product anywhere in the world -

a. Concepts of Freedom to operate (FTO) search and analysis for patents, Exclusivity and SPC status check

3.4 : Other IPR checks like trademarks, copyrights (for printed data on leaflets, packages etc.)

a. Putting IPR related disclaimers while advertising product list or selling products.

References:

- H.Jackson Knight, *Patent Strategy for Researchers and Research Managers* 2nd ed, John Wiley and Sons

Unit 4: Packaging in Pharma industry **15 Lectures**

3.1 : Introduction to Packaging

3.2 : Fundamentals of Distribution

3.3 : Packaging Forms & their Significance

3.4 : Packaging Materials (covering basic manufacturing process, applications and significance)

3.5 : Paper, Paper Board and CFB Glass, metals, Basic Polymer based materials, Polymer based composite materials

3.6 : Ancillary Mats

3.7 : Package Material Testing

3.8 : Compatibility & Migration Studies

3.9 : Accelerated Shelf Life Testing - Theory and Problems

3.10 : GMP

3.11 : Packaging Validation

3.12 : Packaging Laws and regulatory compliance

3.13 : Labeling and Inserts

References:

- Richard Friary, *Jobs in the Drug Industry*, Academic Press

Semester II – Theory

Paper Code: SIPSBN23
Chromatography & Spectroscopy-II

Learning Objectives:

- *To familiarize students with HPTLC, HPLC, GC, AAS, ICP, CD, ORD, X-ray diffraction with emphasis being on instrumentation, its application and troubleshooting.*

- *To introduce students to Hyphenated techniques*

Unit 1: HPTLC **15 Lectures**

1.1 : Principles and Instrumentation
1.2 : HPTLC vs TLC
1.3 : Densitometry & quantitation in HPTLC
1.4 : HPTLC in fingerprinting & QC
1.5 : Troubleshooting
1.6 : Applications of HPTLC

References:

- Dr. P.D. Sethi, *HPTLC High Performance Thin Layer Chromatography*
- Garry D. Christian, *Analytical Chemistry* 5th ed, John Wiley and Sons Inc
- Karel Eckschlager, Klans Danzer, Information *Theory in Analytical Chemistry*, John Wiley and Sons
- Douglas A. Skoog, *Principles of Instrumental Analysis*, Saunders College Publishing
- Chung Chow Chan, Y.C. Lee, *Analytical Method Validation and Instrumental Performance Verification*, Wiley Interscience
- Raymond P.W. Scott, *Chromatographic Detectors Design Function and Operation*, Marcel Dekker Inc

Unit 2: HPLC - II **15 Lectures**

2.1 : Chiral HPLC
2.2 : Column switching in HPLC
2.3 : Gradient reverse-phase HPLC
2.4 : Column conditions
2.5 : Automation in HPLC
2.6 : HPLC detectors
Introduction
Principles of detection
Universal and Specific
Detectors
Detector response
Sensitivity considerations
Selectivity
2.7 : Manual and Electronic data Processing
2.8 : Troubleshooting
2.9 : Applications of HPLC
2.10 : UPLC

2.11 : LC
2.12 : 2D chromatography
2.13 : Preparative chromatography

References:

- Douglas A. Skoog, *Principles of Instrumental Analysis,* Saunders College Publishing
- G. Subramanian, *Preparative and Process Scale Liquid Chromatography*, Ellis Horwood
- Raymond P.W. Scott, *Chromatographic Detectors Design Function and Operation*, Marcel Dekker Inc
- W.M.A. Niessen, *Liquid Chromatography Mass Spectrometry* 2nd ed, Marcel Dekker Inc

Unit 3: GC - II **15 Lectures**

3.1 : Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD)
3.2 : Derivatisation for GC
3.3 : GC strategy for analysis involving biological matrices
3.4 : Troubleshooting
3.5 : Applications

References:

- Douglas A. Skoog, *Principles of Instrumental Analysis,* Saunders College Publishing
- Chung Chow Chan, Y.C. Lee, *Analytical Method Validation and Instrumental Performance Verification*, Wiley Interscience
- Raymond P.W. Scott, *Chromatographic Detectors Design Function and Operation*, Marcel Dekker Inc
- D.J. David, *Gas Chromatographic Detectors*, John Wiley & Sons

Unit 4: Spectroscopy - II **15 Lectures**

4.1 : Theory and applications of;
i. Circular Dichroism (CD)
ii. Optical Rotary Dispersion (ORD)
4.2 : Emission spectroscopy
4.3 : Principles, instrumentation and applications of
i. Flame photometry
ii. Atomic Emission Spectroscopy
4.4 : AAS
d. Principles & Instrumentation
ii. Applications
4.5 : ICP
i. Principles & Instrumentation
ii. Applications
4.6 : X – ray diffraction
i. Principles & Instrumentation
ii. Applications

References:

- Douglas A. Skoog, *Principles of Instrumental Analysis,* Saunders College Publishing
- Roy M. Harrison, Spyridon Rapsomanikis, *Environmental Analysis Using Chromatography Interfaced with Atomic Spectroscopy*, Ellis Horwood Ltd
- James W. Robinson, *Practical Handbook of Spectroscopy*, CRC Press

- G.L. Moore, *Introduction to Inductively Coupled Plasma Atomic Emission Spectrometry*, Elsevier
- Richard D Beaty, Concepts, *Instrumentation and Techniques in Atomic Absorption Spectrophotometry*. Perkin-Elmer
- A-Knowles, C. Burgess, *Practical Absorption Spectrometry*, Chapman & Hall
- Takekiyo Matsoo, Richard M. Capridi, Michael L. Gross, Yousuke Seyama, *Biological Mass Spectrometry Present and Future*, John Wiley and Sons
- Barbara Stuart, *Modern Infrared Spectroscopy* - ACOL, John Wiley and Sons
- Irving Sunshine, *Handbook of Spectrophotometric Data of Drugs*, CRC Press

Semester II – Theory

Paper Code: SIPSBN24
New Drug Development, Immunoassays, Pharmacokinetics, Laboratory Safety Measures

Learning Objectives:

- *To introduce students to new chemical entity.*
- *To familiarize students with basic concepts of Immunoassay and Eliza and its practical applications.*
- *To introduce students various concepts of Pharmacokinetcs & pharmacodynamics, parameters, techniques and models involved.*
- *To introduce students basic concept of drug, its formulation, concepts of drug metabolism, ADR and SAE*

Unit 1: NCE and its development into a New Drug and Enzymes **15 Lectures**

1.1 : What is NCE?
1.2 : Stages in the development of NCE
1.3 : Preclinical studies on NCE
1.4 : Enzyme as Therapeutics agents, as diagnostics, as catalyst in processes as drug target

References:

- WHO, *Specification for the Identity and Purity of some enzymes and certain other substances*,W.H.O
- Richard A.Guarino, *New Drug Approval Process*, Marcel Dekker
- Michael G.Palfregman , Peter McCann ,Walter Lovenberg ,Joseph G.Temple ,Albert Sjoerdsrna *Enzymes as Targets for Drug Design*, Academic

Unit 2: Immunoassay & ELISA **15 Lectures**

2.1 : Introduction
2.2 : Definitions
2.3 : Theory
2.4 : Requirements for immunoassay
2.5 : Practical aspects
2.6 : Requirements for immunoassay
2.7 : Practical aspects
2.8 : Data handling
2.9 : Advantages of immunoassay
2.10 : Principles and instrumentation in ELISA
2.11 : Applications of ELISA
2.12 : Types of Detection systems

References:

Alice J. Cunningham, *Introduction to Bioanalytical Sensors*, John Wiley and Sons

Unit 3: Pharmacokinetics and Pharmacodynamics **15 Lectures**

3.1 : Basic concepts of Pharmacokinetics & pharmacodynamics
3.2 : Different pharmacokinetic & pharmacodynamics parameters and their meanings
3.3 : Basic techniques of evaluating Pharmacokinetic & pharmacodynamics parameters
3.4 : Basic types of models in pharmacokinetics & pharmacodynamics

References:

- Randoll C. Baset, *Advances in Analytical Toxicology* Vol 2, Year Book Medical Publishers
- Aspi F. Golwalla, Sharukh A. Golwalla, *ABC of Medicine*, A.F. Golwalla
- Codric M. Smith, Alan M. Reynard, *Textbook of Pharmacology*, W.B. Saunders Comp
- Milo Gibaldi, *Biopharmaceutics and Clinical Pharmacokinetics* 4th ed., Lea and Febiger
- David B. Jack, *Handbook of Clinical Pharmacokinetic Data*, Macmillan Publisher
- Betram G. Katzung, *Basic and Clinical Pharmacology* 4th ed., Prentice-Hall
- Peter G. Welling, P*harmacokinetics*, Marcel Dekker

Unit 4: Drug properties **15 Lectures**

4.1 : General classification of Drugs and their formulations
4.2 : Drug – Route of entry, Absorption and Distribution with examples
4.3 : Concepts of Drug Metabolism & elimination with examples
4.4 : Adverse Drug reactions (ADRs)
4.5 : Serious Adverse Events (SAEs)

References:

- Lily Y.Young,*Microbial Transformation and Degradation of Toxic*, Dermot Diamond, John Wiley & Sons
- M.D.B.Stephens, *Detection of New Adverse Drug Reactions*, Macmillan Publisher
- Ivan H.Stockley, Drug Interactions -*A Source Book of Adverse Interactions their Mechanisms Clinical Importance & Management*, Blackwell Scientific Publications
- Gene S.Gilbert, *Drug Safety Assessment in Clinical Trials*, Marcel Dekker

M.Sc. Bioanalytical Sciences Syllabus (Autonomous)
Choice Based Credit System (With effect from academic year 2019-20)

Semester II – Practical I (SIPSBNP21)

Based on SIPSBN21

- SPE of a modern drug from formulation (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.
- SPE of a modern drug from plasma (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.)
- Prepare specific reagents and conduct qualitative test for the presence of alkaloids, tannins, lignans, steroids and glycosides using TLC. Compare the results using standards (if available).
- Preparation of Herbarium of following medicinal plants;
  1) Asteracantha longifolia
  2) Trigonella foenum
  3) Clitoria ternatea
  4) Coriandrum sativum
  5) Achyranthus aspera
  6) Scoparia dulcis
  7) Amaranthus spinosa
  8) Phyllanthus amarus
  9) Calotropis gigantea
  10) Vitex negundo

  Individual student must **submit** herbaria of ANY THREE from the above list but in each institution herbarium of all the listed plants must be prepared.
- Preparation of calibration graphs for Li, Na, and K by flame Photometry using their solutions of appropriate concentrations and studying interference of
  i) K in Na estimation
  OR
  ii) Na in Li estimation
  OR
  iii) Li in K estimation
- Determination of percentage purity of $CaCO_3$/$MgCO_3$ by
  i) Titrimetry
  ii) Complexometry
  iii) IE chromatography
- Comparison of classical and modern method of extraction of phytoconstituent of medicinal plants
- Effect of drying on phytoconstituents (Terpenes, alkaloids, tannins)
- Phytochemical variation within a species using HPLC/HPTLC

Semester II – Practical II (SIPSBNP22)

Based on SIPSBN22

- Students must submit a Report of the Industrial Visits including Presentation of the industrial visit.
- Patent Claim Drafting
- Accelerated stability studies of various formulations or drugs with respect to Temperature (b) Effect of buffers / pH dependent (2 – 4 Expts.)
- Test for degradation of compounds using TLC for any two drugs.
- Stability testing of solution and solid dosage forms for photo degradation. (2 experiments).
- Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
- Stability studies of drugs in dosage forms at 25℃, 60% RH and 40℃, 75% RH and at different pressures

Semester II –Practical III (SIPSBNP23)

Based on SIPSBN23

- HPTLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)

- HPTLC fingerprinting of Herbal raw material (e.g. *Asteracantha longifolia*, *Ricinus communis*, *Calotropis gigantea*)

- HPTLC detection of herbal raw material from its formulations (e.g. *Asteracantha longifolia* from Lukol/ Speman, *Vitex negundo* from Panchgun Taila, *Glycyrrhiza glabra* from Anu Taila)

- Gas Chromatographic separation of solutes from their matrix (e.g. Diclofenac sodium from its formulation, Methanol from plasma etc.)

- Determination of Caffeine from a given sample by
  i) HPTLC

  ii) HPLC

  iii) UV

Semester II – Practical IV (SIPSBNP24)

Based on SIPSBN24

- Immunoassay of HEPALISA in serum.
- Immunoassay for HCG in urine
- Immunoassay of T3 and T4 by RIA/IRMA
- Calculation of different Pharmacokinetic parameters like k_a, k_e, t½, C_{max}, T_{max} and AUC from the given blood data.

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4. Allen J. Bard, Electroanalytical Chemistry, A series of Advances Volume – 13, Marcel Dekker, Inc; New York
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8. Dale G.Deutsch, Analytical Aspects of Drug Testing, John Wiley and Sons
9. Rober D.Brown, Introduction to Instrumental Analysis, Mcgraw-Hill International Ed.
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15. Peter Roper, Shaura, Burke, Richard Lawn,Vicki Barwick and Ron Walker, Applications of Reference Materials in Analytical Chemistry
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26. Jack Cazes, Chromatographic Analysis of Pharmaceuticals, Marcel Dekker Inc
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29. K.Robards, Principles and Practice of Modern Chromatographic Methods, Academic Press
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and Sons
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50. Michael Pelczar, E.C.G Chan, Noel R.Krieg, Microbiology, McGraw Hill
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